

Exhibit 13

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re Pharmaceutical Industry)	
Average Wholesale Price)	
Litigation)	MDL No. 1456
)	Master File No. 01-12257-PBS
This document relates to:)	
UNITED STATES OF AMERICA)	
ex rel. VEN-A-CARE OF THE)	
FLORIDA KEYS, INC.)	
)	
Plaintiff,)	
)	
v.)	
)	
ABBOTT LABORATORIES, INC.)	
)	
Defendant.)	
)	
CIVIL ACTION NO. 06-11337-PBS)	
)	

**ORDER RE: SUBMITTED DOCUMENTS
FOR IN CAMERA REVIEW**

November 5, 2008

Saris, U.S.D.J.

In this *qui tam* action under the False Claims Act, 31 U.S.C. §§ 3729 et seq. and state law,¹ the government has submitted twelve documents for in camera review which it contends are protected by the deliberative process privilege. During discovery, the government produced 350,000 pages of documents; its privilege logs listed 451 documents (originally 600 documents). Defendant Abbott Laboratories, Inc. (Abbott) moved

¹ The government also brings claims of fraud and unjust enrichment.

to compel and the Court issued a margin order on August 13, 2007 to which both parties objected. On appeal, the Court denied the motion to compel production or review all of the documents. However, it ordered Magistrate Judge Bowler to conduct an in camera review of certain documents, which she did. Not content, Abbott pressed for interlocutory review. The dispute has prompted extensive briefing.

After hearing, the Court ordered the government to produce all non-privileged documents which the government withheld from production based on the deliberative process privilege which relate to "cross-subsidization" or "mega-spreads" for infusion and inhalation drugs. Abbott vigorously contends that it is entitled to review all documents relevant to the government's knowledge that the Average Wholesale Price ("AWP") listed by drug companies in publications relied on by the government to reimburse for infusion and inhalation drugs was not a true price, and that there was a "spread" between the price actually paid by providers and the price reported to the government.

The government parries sharply that government knowledge is not a defense to a False Claims Act charge and therefore defendant has no need for the privileged documents. Moreover, it points out that spreads for Abbott multi-source drugs at issue in this litigation range from 275% to 1784% with the majority of the spreads exceeding 1000%. Thus even if the government knew of smaller spreads of 25 percent, and permitted these spreads to

cross-subsidize the cost of drug administration, in the government's view, this knowledge is irrelevant to its core contention of fraudulent mega-spreads.

The Court has read each of the documents submitted by the government in camera, and orders that some documents be produced for the reasons stated below.

I. FACTUAL BACKGROUND

The government's complaint against Abbott alleges that Abbott engaged in a fraudulent scheme that caused the Medicare and Medicaid programs to pay excessive reimbursement to Abbott's customers, medical providers such as pharmacies, physicians, hospitals, and clinics. In order to perpetrate this scheme of fraud, Abbott allegedly reported false or misleading pricing information - generally in the form of AWP's - about its products to several price reporting services. In order to compile their pricing compendia, publishers receive drug pricing information from the manufacturers of the various drugs, such as Abbott, and then base their published pricing data on this information. The government, in turn, utilizes these reporting publications to determine its reimbursement prices. Because the drug manufacturers control the prices that are reported by the compendia, they can effectively fix the AWP of their own drugs.

In general, this pricing scheme allows drug manufacturers to set reimbursement prices to levels well above the providers'

acquisition costs. The difference between the reported AWP of a prescription drug and the drug's actual acquisition cost is referred to as the drug's "spread." By inflating the prices provided to the compendia, and thus pumping up the AWP of the drug, pharmaceutical manufacturers increase a drug's spread. Plaintiff alleges that this increase in spread consequently magnifies a drug's profitability to the financial benefit of the providers, like pharmacies. The complaint alleges that Abbott marketed these inflated spreads to its customers.

The effect that increasing a drug's reported AWP has on the price paid by the federal government depends on whether the drug is a single-source drug or a multi-source drug. For single-source drugs, the government's reimbursement rates for Medicare were set by statute at 95% of AWP from 1998 until 2003; before 1998, rates were set at 100% of AWP or estimated acquisition cost. 42 U.S.C. § 1395u(o); 42 C.F.R. § 405.517 (1998) (amended 1998, 2004); 42 C.F.R. § 405.517 (1999) (amended 2004); 42 C.F.R. § 405.517 (2003) (amended 2004). For multi-source drugs, like the ones at issue here, the government set its reimbursement figures from 1998 to 2003 at 95% of the lesser of the median of all generic AWP or the lowest branded AWP for a given drug; before 1998, multi-source drugs were reimbursed at 100% of the median generic AWP or estimated acquisition cost. 42 U.S.C. § 1395u(o); 42 C.F.R. § 405.517 (1998) (amended 1998, 2004); 42

C.F.R. § 405.517 (1999) (amended 2004); 42 C.F.R. § 405.517 (2003) (amended 2004); see also In re Pharm. Indus. Average Wholesale Price Litig., 230 F.R.D. 61, 70 (D. Mass. 2005).

Specifically, the complaint alleges that in 2001, Abbott sold several drugs with grossly inflated AWP's: Vancomycin (an antibiotic), a 5% Dextrose Solution, and a 0.9% Sodium Chloride Solution. For Vancomycin, the AWP reported by Abbott was \$274.91. However, the actual acquisition cost of the drug was \$67.95. Therefore, the "spread" was 304.57%. The Dextrose Solution and the Sodium Chloride Solution had even more inflated spreads; the Dextrose Solution was marked up by 917.22%, and the Sodium Chloride Solution had a spread of 1046.92%. The complaint alleges that Abbott reported these false inflated prices to the compendia, knowing that the government would use this information to set its reimbursement rates. As a result, the government charges that it overpaid for Abbott's drugs.

II. DISCUSSION

1. Deliberative Process Privilege

As a threshold matter, the Court must determine whether the deliberative process privilege is applicable to the documents for which the Government is asserting the privilege. The deliberative process privilege covers "documents reflecting advisory opinions, recommendations and deliberations comprising part of a process by which governmental decisions and policies

are formulated." Dep't of the Interior v. Klamath Water Users Protective Ass'n, 532 U.S. 1, 8 (2001) (quoting NLRB v. Sears, Roebuck & Co., 421 U.S. 132, 150 (1975)). "The deliberative process privilege rests on the obvious realization that officials will not communicate candidly among themselves if each remark is a potential item of discovery and front page news, and its object is to enhance the quality of agency decisions by protecting open and frank discussion among those who make them within the Government." Klamath Water Users Protective Ass'n, 532 U.S. at 8-9 (internal quotation marks and citations omitted). See also EPA v. Mink, 410 U.S. 73, 87 (1972) ("[I]t would be impossible to have any frank discussions of legal or policy matters in writing if all such writings were to be subjected to public scrutiny.") (internal quotation marks and citation omitted), superseded by statute in other respects, Pub. L. No. 93-502, 88 Stat. 1561 (1974); Carter v. U.S. Dep't of Commerce, 307 F.3d 1084, 1089 (9th Cir. 2002) ("The purpose of this privilege is to allow agencies freely to explore possibilities, engage in internal debates, or play devil's advocate without fear of public scrutiny.") (internal quotation marks and citation omitted).

To qualify for the deliberative process privilege, a document must be (1) "predecisional," that is, prior to the adoption of the agency policy, and (2) "deliberative," that is, related to the policy-making process. Texaco P.R., Inc. v. Dep't of Consumer Affairs, 60 F.3d 867, 884 (1st Cir. 1995) (quoting

Nat'l Wildlife Fed'n v. U.S. Forest Serv., 861 F.2d 1114, 1116 (9th Cir. 1988)). "A predecisional document may be virtually any document that contains personal opinions and is designed to assist agency decision-makers in making their decisions." Mo. Coal. for the Env't Found. v. U.S. Army Corps of Eng'rs, 542 F.3d 1204, 1211 (8th Cir. 2008). "A document will be considered 'predecisional' if the agency can (i) pinpoint the specific agency decision to which the document correlates, (ii) establish that its author prepared the document for the purpose of assisting the agency official charged with making the agency decision, and (iii) verify that the document precedes, in temporal sequence, the decision to which it relates." Providence Journal Co. v. U.S. Dep't of the Army, 981 F.2d 552, 557 (1st Cir. 1992) (internal quotation marks and citations omitted). A document is 'deliberative' if it "(i) formed an essential link in a specified consultative process, (ii) reflect[s] the personal opinions of the writer rather than the policy of the agency, and (iii) if released, would inaccurately reflect or prematurely disclose the views of the agency." Id. at 559 (internal quotation marks and citations omitted). Put another way, "a document is 'predecisional' if it precedes in time the decision to which it was applied and it is 'deliberative' if it constitutes a statement of opinion regarding final policy rather than a description of the ultimate policy itself." United States v. Cicilline, No. 07-10008-NMG, 2008 WL 427286, at *1 (D. Mass.

Feb. 13, 2008).

The deliberative process privilege does not shield documents that simply state or explain a decision the Government has already made, Sears, Roebuck & Co., 421 U.S. at 151-152, or protect material that is purely factual, unless the material is so inextricably intertwined with the deliberative sections of documents that its disclosure would inevitably reveal the Government's deliberations. Providence Journal Co., 981 F.2d at 562. Even factual material is protected if its disclosure "would expose an agency's decisionmaking process in such a way as to discourage candid discussion within the agency and thereby undermine the agency's ability to perform its functions." Id. at 562 (quoting Quarles v. Dep't of Navy, 893 F.2d 390, 392 (D.C. Cir. 1990)) (internal quotation marks and citation omitted).

Even if a document is both predecisional and deliberative, nondisclosure is not automatic. Texaco P.R., Inc., 60 F.3d at 885. The privilege "is a qualified one" and "is not absolute." Id. (internal citations omitted). In exercising its discretion as to whether the deliberative process privilege requires nondisclosure, a court "should consider, among other things, the interests of the litigants, society's interest in the accuracy and integrity of factfinding, and the public's interest in honest, effective government." Id. The Court must balance the public interest in the protection of the deliberative process against the movant's particularized need for the information as

evidence in the case before it. See e.g., Comm. for Nuclear Responsibility, Inc. v. Seaborg, 463 F.2d 788, 791 (D.C. Cir. 1971); Carl Zeiss Stiftung v. V.E.B. Carl Zeiss, Jena, 40 F.R.D. 318, 327 (D.D.C. 1966), aff'd sub nom. V.E.B. Carl Zeiss, Jena v. Clark, 384 F.2d 979 (D.C. Cir. 1967). To compel disclosure, the movant must "make a showing of necessity sufficient to outweigh the adverse effects the production would engender." Id. at 328-329.

Courts consider numerous factors when balancing the competing interests involved, including:

- (i) the relevance of the evidence sought to be protected;
- (ii) the availability of other evidence; (iii) the 'seriousness' of the litigation and the issues involved;
- (iv) the role of the government in the litigation; and
- (v) the possibility of future timidity by government employees who will be forced to recognize that their secrets are violable.

In re Franklin Nat'l Bank Sec. Litig., 478 F. Supp. 577, 583 (E.D.N.Y. 1979). "While this list does not purport to be an exhaustive list of factors a court might consider, it is at least a floor upon which to balance sufficiently the competing interests of the parties and the federal agency." In re Bankers Trust Co., 61 F.3d 465, 472 (6th Cir. 1995).

In conducting a balancing test, a court should conduct an individualized review of each piece of evidence "to insure that the balance between petitioners' claims of irrelevance and privilege and plaintiffs' asserted need for the documents is

correctly struck." Kerr v. U.S. Dist. Court for the N. Dist. of Cal., 426 U.S. 394, 405 (1976).

2. Government Knowledge

The bone of contention between the parties is whether the government's knowledge of spreads is relevant. The Court had previously ordered the government to produce documents which reference Abbott's drugs, but Abbott insists it is entitled to documents referencing the government's knowledge of spreads in general, and similar multi-source drugs in particular. Abbott contends that the Government has waived its right to assert the deliberative process privilege because the government has put its knowledge and deliberations at issue by asserting fraud-based claims. The United States disagrees, arguing that the privilege is applicable because government knowledge is not relevant to a defense of a False Claims Act claim unless the knowledge of those prices was communicated to Abbott. Therefore, the first issue which must be addressed is whether the government's knowledge or deliberations are placed at issue when the government asserts an FCA claim or a fraud-based claim.

As the complaint alleges, this lawsuit is premised on the notion that the federal and state governments were misled into paying "excessive reimbursement" for the Subject Drugs through the Medicare and Medicaid programs. The government alleges that prices for the subject drugs reported in the pricing compendia

were false, fraudulent, and inflated, and that the Medicare and Medicaid programs relied upon these prices to set reimbursement rates for Abbott's customers. The government further alleges that it acted in justifiable reliance upon Abbott's misrepresentations, and that it would not have paid for the products at issue if the true facts of Abbott's false price reporting had been known to the United States.

Abbott contends that the documents and testimony regarding the Government's knowledge as to whether published AWP's equaled or approximated actual market prices is directly relevant to whether the government justifiably relied on those prices and whether the government was misled. Case law involving the government knowledge defense under the False Claims Act is evolving. As the Court addressed in In re Pharm. Indus. Average Wholesale Price Litig., 478 F. Supp. 2d 164, 174 (D. Mass. 2007):

In some circumstances, the government's 'knowledge [of a fraud] effectively negates the fraud or falsity required by the FCA.' Am. Contract Servs. v. Allied Mold & Die, Inc., 94 Cal. App. 4th 854, 864, 114 Cal. Rptr. 2d 773 (Cal. Ct. App. 2001). Some courts have held that governmental knowledge will vitiate a possible FCA claim where 'the government knows and approves of the particulars of a claim for payment before that claim is presented.' United States ex rel. Durholz v. FKW Inc., 189 F.3d 542, 545 (7th Cir. 1999) (emphasis added). In these instances, 'the presenter cannot be said to have knowingly presented a fraudulent or false claim.' Id. Thus, there may be 'occasions when the government's knowledge of or cooperation with a contractor's actions is so extensive that the contractor could not as a matter of law possess the requisite state of mind to be liable under the FCA.' Id.; see also United States ex rel. Hagood v. Sonoma

County Water Agency, 929 F.2d 1416, 1421 (9th Cir. 1991) (holding that knowledge by federal officials may 'show that the defendant did not submit its claim in deliberate ignorance or reckless disregard of the truth'). However, government knowledge is not an automatic bar to suit under the FCA. United States ex rel Butler v. Hughes Helicopters, Inc., 71 F.3d 321, 327 (9th Cir. 1995); Shaw v. AAA Eng'g & Drafting, Inc., 213 F.3d 519, 534-35 (10th Cir. 2000).

Therefore, "courts have had to decide case by case whether a FCA claim based on information in the government's possession can succeed." Butler, 71 F.3d at 326.

Government knowledge could conceivably be relevant to two elements of the False Claims Act: the falsity of the claim and the defendant's state of mind. As to falsity, "there appears to be an emerging consensus (not without significant authority to the contrary) that it is not negated by government knowledge." 1 John T. Boese, Civil False Claims and Qui Tam Actions § 2.03[F] (3d ed. 2008). The Ninth Circuit has stated that "what constitutes the offense is not intent to deceive but knowing presentation of a claim that is either 'fraudulent' or simply 'false'. . . . That the relevant government officials know of the falsity is not in itself a defense." Hagood, 929 F.2d at 1421. Numerous other courts have concurred. See United States ex rel. Kreindler & Kreindler v. United Techs. Corp., 985 F.2d 1148, 1156 (2d Cir. 1993); United States ex rel. Becker v. Westinghouse Savannah River Co., 305 F.3d 284, 289 (4th Cir. 2002); Tyger Constr. Co. v. United States, 28 Fed. Cl. 35, 60

(Fed. Cl. 1993); United States ex rel. Mayman v. Martin Marietta Corp., 894 F. Supp. 218, 223 (D. Md. 1995).

Even those cases that have found government knowledge to negate the element of falsity have required that the government possess knowledge of the actual true facts of the claim, not simply knowledge that the claim is generally false; some have further required that the government actually approve of those true facts. For instance, the Seventh Circuit found "the government's knowledge effectively negates the fraud or falsity required by the FCA" where "the government knows and approves of *the particulars of a claim* for payment before that claim is presented. . . ." Durcholz, 189 F.3d at 545 (emphasis added). That is, there can be no falsity where "[t]he government knew what it wanted, and. . . got what it paid for." Id. Further, these cases also seem to rely on the fact that the government *approves* of the false claim, finding no falsity only where it is alleged that "the government was defrauded by the very activities its agents ordered" and that the defendant somehow "defraud[ed] the government by following the government's explicit directions." Id.

Similarly, while some courts have found that government knowledge can prevent the defendant from forming the requisite state of mind (knowing that the claim is false or fraudulent), they have done so only where the government's knowledge as to the

true facts is extensive and in some cases where the government has actively approved of the underlying facts. According to the Tenth Circuit, "there may. . . be occasions when the government's knowledge of or cooperation with a [defendant's] actions is so extensive that the [defendant] could not as a matter of law possess the requisite state of mind to be liable under the FCA." Shaw, 213 F.3d at 534. Likewise, the Fourth Circuit held that "the government's knowledge of the facts underlying an allegedly false record or statement can negate the scienter required for an FCA violation"; specifically, that the government's "*full knowledge of the material facts* underlying [a defendant's representations]. . . negates any knowledge that [the defendant] had regarding the truth or falsity of those representations." Becker, 305 F.3d at 289. For instance, where the defendant and the government "so completely cooperated and shared all information," claims could not be knowingly false. Butler, 71 F.3d at 327.

As one court put it, a defendant's "disclosure. . . to the government is relevant, not because government knowledge of a misrepresentation shields a [defendant] from liability, but because evidence of disclosure may 'point[] persuasively away from any conclusion that [the defendant] made a knowing misrepresentation.' In other words, disclosure. . . may establish that the defendant did not 'knowingly' submit false

claims. . . ." United States v. Newport News Shipbuilding Inc., 276 F. Supp. 2d 539, 564 (E.D. Va. 2003). That "the government knew of [the defendant's] mistakes and limitations, and that [the defendant] was open with the government about them, suggests that. . . [the defendant] was not cheating the government. . . ." Wang v. FMC Corp., 975 F.2d 1412, 1421 (9th Cir. 1992).

The government's argument is thus premature. Although the government knowledge defense may not ultimately prevail, Abbott has the right during discovery to see documents reflecting the government's knowledge about spreads in order to mount the defense. The government has conceded that at some point it knew about a 25 percent spread, sometimes called a yardstick, and will not be asserting damages from any price inflation in this narrow range. However, this concession does not mean that Abbott is not entitled to peruse documents reflecting the extent of the government's knowledge that AWP's did not reflect actual acquisition costs. While knowledge of a small spread certainly does not equate with approval of the mega-spreads here, Abbott has the need to see what the government knew about spreads and when it knew it in order to see if a government knowledge defense will fly. Moreover, the government has asserted a common law fraud claim so Abbott has the right to explore reasonable reliance. See Dep't of Econ. Dev. v. Arthur Anderson & Co., 139 F.R.D. 295, 299 (S.D.N.Y. 1991) (holding that the assertion of

claims of fraud "necessarily places at issue questions of knowledge, justifiable reliance and causation.")

The government also contends that the defendant has had extensive depositions on the issue of government knowledge and therefore has no need of these documents. Abbott denies this and states that the government curtailed the deposition testimony of witnesses, many of whom had hazy memories. However, with respect to the documents submitted, it is difficult on this record for the Court to match up each document with prior discovery to see if the issue has been adequately vetted.

3. Individualized Review of Documents²

With the above standard and disputes in mind, based on a review of the documents, I make the following findings.

²The Norwalk affidavit does not expressly discuss any of these documents.

Tab 1(A): Briefing Material - Physician Fee Schedule
(Dated September 5, 1991)

The cover memorandum (HHD 816-001) is not privileged because it is not deliberative. The following pages are privileged in that they are predecisional and deliberative (HD 816-002 to 0021; HHD 816-0022 to 0024). Because they are largely irrelevant to the issues in this litigation, defendant has no need for the documents.

The section entitled "Payment for Drugs" (HHD 816-0021) is pre-decisional and deliberative because it precedes, and discusses alternatives to, the proposed final regulation. However, Defendant's need for the information which reflects the government's knowledge of the inaccuracy of the AWP's outweighs the government's interests in frank discussion. As these deliberations happened 17 years ago, it is hard to imagine that disclosure will chill future timid government employees.

Tab 1(B): Draft Final Rule: Fee Schedule for Physicians' Services -- CONCURRENCE WITH COMMENTS
(Dated October 25, 1991)

The Memorandum from the Principal Deputy Inspector General to the Executive Secretariat (document HHD 816-0025 to 0027) is protected by the deliberative process privilege, but Abbott's need for the documents outweighs the government's interest in non-disclosure because it discusses in 1991 the deficiencies in using AWP, particularly for multiple source drugs.

Tab 1(C): Draft Final Rule: Fee Schedule for Physicians' Services - COMMENTS (Dated November 7, 1991)

For the reasons stated above, the document is protected by the deliberative process privilege but defendant's need outweighs the government's interest.

Tab 2(A): Medicare Payments for Drugs Using Department of

Justice Data - INFORMATION

This document created in 2000 is not fully protected by the deliberative process privilege because it appears to be primarily factual, not deliberative. It seems to discuss a decision that had already been made by the Secretary. The government contends that the material relates to the proposal to allow Medicare carriers to use pricing information obtained by the Department of Justice when determining payout amounts for certain drugs. Assuming it is deliberative and pre-decisional, defendant's litigation need for the information regarding when the government had knowledge of the spreads in inhalation drugs outweighs the government's interest. However, the earlier draft (HHD 809-0014 to 0015) need not be produced.

Tab 2(B): Marked up Letter to the Honorable Tom Bliley

The marked-up drafts are privileged, and defendant's need for the draft documents does not outweigh the government's interest.

Tab 2(C): Short Term Options for the Average Wholesale Price (AWP) Proposed Regulation(Dated April 30, 2003)

As the heading of the document demonstrates, the documents are covered by the deliberative process privilege. They are irrelevant because they were created after the claims period which runs only through 2001. Accordingly, defendant's need for the documents does not outweigh the government's interest.

Tab 2(D): AWP - Adjusting Reimbursement Through in Market Pricing (Dated January 9, 2003)

This document is protected by the deliberative process privilege and is irrelevant because it post-dates the dispute in this litigation. It need not be produced.

Tab 2(E): Practice Expenses for Chemotherapy (Dated May 5, 1998)

This document is privileged because it proposes an alternative preamble for a proposed regulation. However, defendant's need outweighs the government's interest because it demonstrates knowledge that drug reimbursements to doctors were higher than actual drug costs.

Tab 2(F): ABC Expose on Nebulizer Drugs (Dated April 22, 1998)

The document is not privileged because it is neither pre-decisional nor deliberative.

Tab 3(A): OIG Reports on Medicare and Medicaid Pricing of Prescription Drugs - BRIEFING (Dated December 7, 2001)

The document from the Inspector General to the Deputy Secretary is not privileged because it is neither pre-decisional nor deliberative, but rather a survey of reports of the Inspector General.

Tab 3(B): Office of Inspector General (OIG) Draft Report: Medicaid Pharmacy - Actual Acquisition Cost of Generic Prescription Drug Products (A-06-01-00053)

The government asserts that the document is a draft memo from the CMS administrator to the Inspector General relating to a 2001 OIG draft report. Defendant's interests are outweighed by the government's interest because government says the same information is contained in the final draft of the memorandum, which was produced.

Tab 4: Cigna Cover Memo; BPD Memo on Nebulizer Drugs (Dated February 12-13, 1995)

The document was prepared by a medical director employed by a carrier (Cigna), not CMS. It is not privileged because it does not reflect an internal agency deliberation. Even if a carrier's communications to the agency were privileged, defendant's need outweighs any governmental interest because it informs the government of mega-spreads for nebulizer drugs in 1995.

ORDER

The government shall produce documents as provided above in this opinion.

S/PATTI B. SARIS

United States District Judge